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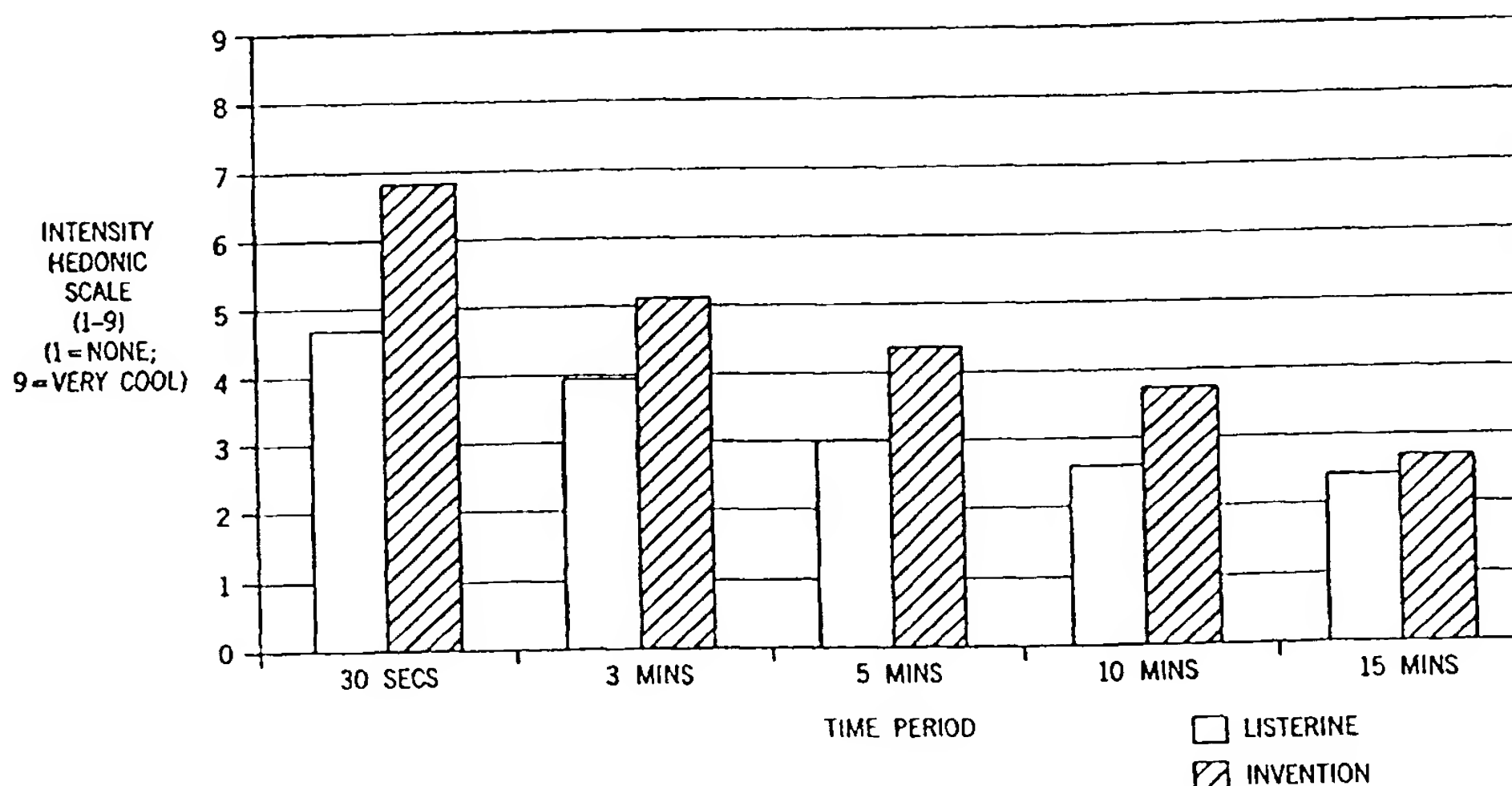
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(21) International Application Number: PCT/US99/23811 (22) International Filing Date: 14 October 1999 (14.10.99) (30) Priority Data: 09/173,998 16 October 1998 (16.10.98) US (71) Applicant: FUISZ TECHNOLOGIES LTD. [US/US]; 14555 Avion at Lakeside, Chantilly, VA 20151 (US). (72) Inventors: CHERUKURI, Subraman, R.; 10241 Britten Ford Drive, Vienna, VA 22182 (US). CHAU, Tommy, L.; 20322 Snowpoint Place, Ashburn, VA 20147 (US). TEALE, David, M.; 2814 Emma Lee Drive, #302, Falls Church, VA 22042 (US). CROUSHORN, Paul, M.; 5479 Courtneys Corner Road, Summerduck, VA 22742 (US). (74) Agent: SCHMIDT, Richard, D.; Fuisz Technologies Ltd., 14555 Avion at Lakeside, Chantilly, VA 20151 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZW, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: DRY DEODORIZING COMPOSITION FOR ORAL ADMINISTRATION



(57) Abstract

A dry deodorizing composition for oral administration has at least one carrier material, at least one processing aid, and at least one active ingredient which is selected from the group consisting of deodorizing substances. The formulations is highly storage stable, and provides long-lasting breath freshening protection. The composition provides a refreshing, cooling sensation to the user's oral cavity and has antiseptic and bacteriostatic properties.

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DRY DEODORIZING COMPOSITION FOR ORAL ADMINISTRATION

Field of the Invention

The present invention relates to a deodorizing composition, and more particularly, to a dry, storage stable, orally-administered deodorizing composition which is highly effective as a mouthwash, mouth cleaner and breath freshener. The composition provides a substantially alcohol-free (ethanol-free) microparticulate dispersion having oral
5 antiseptic and microbial action. The invention also relates to a method of neutralizing or masking malodor emanating from the mouth and digestive tract, which comprises administering the novel composition herein described.

Background of the Invention

Malodorous breath and overall body odor have been personal hygiene issues
10 for many years. Food particles and other matter which linger in the area of the mucous membranes and between the teeth and gums contribute significantly to this odor problem. Another primary cause of malodor is the emanation of various sulfur compounds from the mouth and digestive tract. Sulfur is generated in the gut as a result of the breakdown of various high-sulfur foods, and is released from the body through the mouth and pores of
15 the individual. Certain food substances, such as garlic and onions, are notorious for generating the sulfur compounds which cause the unpleasant odor. Garlic eaters typically note a considerable amount of belching and burping for several hours after consumption. As the garlic is digested in the abdominal tract, bursts of gas are generated, and with these bursts comes a rather disagreeable smell. Other substances such as tobacco and alcohol
20 also affect a person's oral hygiene as these substances tend to linger around the mucous membranes inside the mouth. Living organisms such as bacteria and germs are also a contributing factor to oral malodor.

Several substances have now established roles as breath fresheners in the mouthwash, chewing gum and confectionery industries. These include many metallic ions,
25 as well as organic substances such as the oil derived from cardamon seeds. For example,

U.S. Patent No. 4,626,427 is directed to a cardamon seed preparation which is effective against bad breath. Mushroom extract as an active agent is discussed in U.S. Patent No. 5,639,470. In U.S. 4,689,214 a combination of zinc ions and ionone/ketone terpene derivatives is set forth. Terpene compounds are also set forth in U.S. Patent No. 4,814,163.

5 German Patent documents 3,610,179 and 3,733,742 are also directed to breath freshening formulations. Many of these substances concentrate their action in the stomach by neutralizing or masking foul-smelling sulfur compounds from various food sources. Other examples of orally administered deodorizing formulations may be found in U.S. Patent No.s 4,919,918; 5,143,720; 5,688,492 and 5,628,986.

10 Unfortunately, many of the substances and formulations recognized as deodorizers and breath stabilizers are relatively volatile under ambient conditions. They therefore present storage stability problems in such delivery mechanisms as traditional liquid mouthwashes and chewing gum. In addition, many breath fresheners and deodorizing agents react quite readily with one another, thereby reducing their overall
15 breath-freshening capacity rather quickly over time. It is this neutralization problem, as well as the aforesaid volatilization of the actives upon exposure to ambient conditions, that has heretofore inhibited the development of a truly long-lasting orally administered deodorizing formulation in dry particulate form. The consumer is therefore left with the dubious option of toting around containers of liquid mouthwash which are bulky and
20 impractical, and which too often spill their contents at the wrong time. Chewing gums are fine, but are not appropriate in business situations such as meetings.

What is therefore needed in the art is a dry, deodorizing composition for oral administration which dissolves quickly in the mouth, has a palatable taste, and affords the user both instant and long-range breath and body odor protection, even after being
25 rinsed from the mouth or swallowed. The composition should furthermore provide bacteriostatic and antiseptic action, as well as impart a clean, cool or refreshing sensation to the mouth. The formulation should be storage stable over extended periods, such that the individual components do not neutralize or react with one another while on the shelf.

Another desirable attribute of a deodorizing composition should include an
30 ability to be tableted into lozenges which dissolve quickly under the action of saliva. In

this way, the consumer is not left sucking on a candy mint for several minutes in social and business situations where such actions may not be acceptable.

Summary of the Invention

5 These and other objects of the invention are provided by a dry deodorizing composition in particulate form for oral administration which comprises at least one carrier material, at least one processing aid selected from the group consisting of oleaginous substances and at least one active ingredient which is selected from the group consisting of deodorizing substances and cleansers. In at least one embodiment, the formulation
10 provides an antiseptic cleaning or bacteriostatic action, eliminating many of the common germs and bacteria found in the mouth, mucous membranes and between the teeth. In at least one other embodiment, the composition herein described imparts a refreshing and cooling "vapor action" sensation to the oral and nasal passageways. Unlike most commercial liquid mouthwashes available today, the formulation of the invention is
15 substantially alcohol-free (little or no ethanol).

 Also provided as part of the invention is a method of effectively masking or neutralizing/eliminating odors emanating from the mouth, digestive tract and bodily pores which involves the oral administration of the formulation described above. By rinsing the mouth with the composition of the invention, the consumer attains a clean, fresh sensation
20 as a result of having deodorized breath and a cleansed mouth.

 Additionally, the invention provides a tableted, oral deodorizing composition and a method of making same. The composition dissolves quite rapidly in the mouth, and has excellent oral cleansing attributes.

25 Brief Description of the Drawings

 Figure 1 is a photo micrograph at 250X normal size of 0.8 grams of unprocessed mouth deodorizing and cleansing material.

 Figure 2 is a photo micrograph at 250X normal size of 0.8 grams of the same material in Figure 1 after processing according to the procedures herein set forth.

30 Figures 3 - 7 are graphs of comparative test data for the composition of the

invention in one embodiment versus one or more commercial brands of mouthwashes.

Detailed Description of the Preferred Embodiments

The novel dry deodorizing composition of the invention comprises a carrier material as one component. This carrier material is utilized to provide support for, or “piggyback”, the hereinafter described active deodorizing substance(s), especially during preparation of the composition. Carrier materials are typically chosen from the listing of saccharide materials available in the food industry. These materials will include mono, di, tri- and polysaccharide material, either alone or in combination, and their related oligomers, as well as oligosaccharides. By way of illustration, invert sugar, sucrose, fructose, maltose, dextrose, polydextrose, polydextrin, glucose (corn syrup), maltodextrin, corn syrup solids, etc. are just some examples of suitable carrier material. Of these, maltose, maltodextrin and polydextrose are often desirably utilized. Sugar alcohols are also included in the term saccharides. A non-limiting list of sugar alcohols includes the following: sorbitol, mannitol, maltitol, pentitol, isomalt (Palatinit®), xylitol, et al. Sugar derivatives include chemical and enzymatic derivatives and include, but are not limited to, chloro derivatives of sugar such as sucralose. Especially preferred carrier materials for use in the novel dry deodorizing composition are those which may be referred to as “non-sucrose”, and include polydextrose, maltodextrin, isomalt and combinations thereof. The skilled artisan may find that other food-grade raw materials, having the characteristics of the saccharide material set forth above, may also be used as suitable carrier material. For example, certain non-saccharide or “sugarless” material can also constitute the carrier material of the composition.

The carrier component of the composition of the invention will typically constitute about 10 - 98% thereof, more particularly about 50 -95%, and even more desirably about 70-90% of the composition of the invention (unless otherwise stated, all percentages provided herein are weight percentages based on the total weight of the final composition).

Further provided as part of the dry, particulate deodorizing formulation of the invention is one or more active ingredients. These active ingredients may be naturally

or synthetically (man-made) derived and are chosen from those available in the industry with active deodorizing and/or cleansing prowess; they are capable of effectively masking or neutralizing/ eliminating body odor. Typically, the compounds that neutralize odor do so by reacting with the sulfur and other chemical compounds contained in organic substances, particularly food substances, that are responsible for the malodor. Preferred active ingredients include one or more metallic ions along with their equivalent salts, esters or other equivalent compounds thereof. Metallic ions can include, for example, copper and zinc ions. In particular, zinc gluconate, copper gluconate and sodium copper chlorophyllin are desirable. Other metallic ions and inorganic compounds and substances available to the skilled artisan may also be utilized.

Another example of active ingredients includes members of the ionone/ketone terpene compounds utilized as odor neutralizers, particularly odor emanating from the mouth and digestive tract. Of these, a compound known as alpha-ionone may be desirable. This family of compounds is particularly desirable because its members are known to react with sulfur in, for example, garlic and onions, to effectively neutralize the disagreeable smells associated with the normal breakdown of these food substances.

In addition to the foregoing, other recognized deodorizers capable of oral administration may be used as active ingredients. These would include such compounds as menthol, menthone, thymol and eucalyptus. Any of the active ingredients may be available in their raw, unprocessed state, but can also be provided as a commercial preparation in dry powder or liquid form. Other examples of highly desirable active ingredients include the residue from cardamon seeds, such as cardamon oil, which is well-recognized by the skilled artisan for its deodorizing capabilities. Mushroom extract, ginseng, parsley seed extract and sunflower oil may also be desirable. Other naturally derived extracts are also highly suitable. The listing herein provided of suitable active ingredients is by way of illustration only; the skilled artisan may utilize others as well from the myriad of sources now or hereinafter available in the industry. For example, as heretofore stated, those substances which merely mask or "cover up" malodor, instead of fully neutralizing the source of the bad smell, may be chosen as well.

The active ingredient(s) heretofore described will typically comprise from

about 0.001 to 10% of the composition of the invention, and more preferably will usually be within the range of from about 0.01 to 5% thereof. In certain embodiments, it may even be desirable to utilize 0.1 to 3% of the actives as part of the final overall deodorizing formulation. The foregoing percentages may be decreased or increased by the person
5 skilled in the art, depending upon how strong or weak of a final composition is ultimately desired.

The active ingredients heretofore described are preferably provided as part of an encapsulated matrix within the novel deodorizing composition set forth herein. In this way, the actives' deodorizing and/or cleansing prowess is preserved until the
10 composition is taken orally and dissolved in the mouth by an end user. In order to effectively encapsulate the active ingredients, one or more processing aids such as oleaginous material is utilized. It is believed that the oleaginous material surrounds and enrobes individual particles of the active ingredients, thereby creating a matrix of several thousand individually enrobed particles within each serving of the final composition.
15 Suitable oleaginous material includes various food-grade oils and fats available in the industry. Of these, those with emulsifying properties are often particularly desirable. Edible vegetable and animal oils and fats may be utilized for this purpose. Stearine may be utilized as an encapsulating agent, while a fat product marketed under the name DurEm 117 is also efficacious. Canola oil is preferred as well, while medium chain triglyceride
20 (MCT) oils are also desirable. Oleaginous material as encapsulating/processing aids will typically comprise about 0.1 to 10% of the deodorizing composition of the invention, and more desirably will make up from about 1 to 7% thereof.

Various encapsulation techniques may be utilized to provide the encapsulated actives matrix as part of the composition of the invention. In one
25 embodiment, the flash-flow processing techniques set forth in U.S. Patent No. 5,380,473 can be utilized. The techniques of the 473 patent may be further utilized in conjunction with a unique tower device in which material to be encapsulated is provided in free fall by a sprayer at the top of the tower, and an encapsulant material such as oleaginous substances is extruded in the form of droplets to coat and encapsulate the dry, particulate material
30 exiting the tower. Other methods available in the art such as, *e.g.* spray-drying, atomizing

and simple and complex extrusion processes are also within the scope herein set forth. Simple mixing methods with industrial scale mixing equipment (Hobart and Sigma type mixers) may also be utilized to prepare encapsulations.

Further provided as part of the orally administered, dry deodorizing composition of the invention are one or more sweeteners. These are included to impart a palatable sweetness or savoriness to the final formulation. Sweeteners can be chosen from the listing of saccharide material also available to the skilled artisan as the carrier component, or can be different materials from those comprising the carrier material, heretofore described. Sweeteners can include mono-, di- and tri- and polysaccharide materials, either alone or in combination, and their related oligomers. Invert sugar, sucrose, fructose, maltose, dextrose, polydextrose, polydextrin, glucose (corn syrup), maltodextrin (corn syrup solids) etc. are just some examples of suitable sweeteners. Other highly suitable sweeteners include saccharin, aspartame, acesulfame, sucralose, sorbitol, mannitol, maltitol, xylitol as well as other commercially available sweeteners such as the dihydrochalcone compounds, glycyrrhizin, Stevia Rebaudiana (Stevioside), and the hydrogenated starch hydrolysates. Of the foregoing, those sweeteners considered in the industry to be sugarless or non-sucrose are perhaps more preferred. Other sweeteners contemplated by the skilled artisan which are typically utilized in the food or mouthwash industry may also be used. The sweeteners are added in amounts equal to about 0 - 10% of the composition, and preferably within the range of about 0.01 - 5%. More preferably, the sweeteners will comprise about 0.1 - 1% of the final dry deodorizing formulation according to its various embodiments.

Flavoring agents may also be included as part of the deodorizing composition of the invention. These may or may not be recognized as true deodorizers in and of themselves, *i.e.* they may or may not neutralize or even mask odor, but are particularly preferred because they impart an agreeable taste and flavor to the composition in one or more of its various embodiments. Any number of flavoring agents may be utilized (in whatever form), and can be chosen from the listing of suitable natural and synthetic flavoring liquids and powders, etc. available in the industry. An illustrative list of such agents includes such oils as volatile oils and synthetic flavor oils, flavoring

aromatics, liquids, powders, oleoresins and extracts derived from plants, leaves, flowers, fruits, stems, and bark, etc., as well as any combinations thereof. As non-limiting examples, the listing includes those flavoring agents which impart a cooling, refreshing or mint-tasting flavor to the final composition, as for example cinnamon, and those of "mint" origin such as peppermint, spearmint and wintergreen. These flavoring agents can comprise from about 0 - 5% of the composition. Desirably, they will make up about 0.01 - 5% of the formulations herein set forth.

Coloring agents may also be included as part of the novel composition of the invention. Naturally and synthetically-derived food dyes can make up from about 0 to 1%, more preferably about 0.0001 to 0.5% of the final composition.

An optional component of the novel deodorizing formulation herein described is an absorbent material. The absorbent material assists in the absorption of malodorous substances from the mouth and gut. This material should preferably possess bioadhesive properties and have an affinity for the mucous membranes of the mouth under the presence of saliva or other aqueous media, thereby assisting the body's absorption of the active ingredients. An especially preferred absorbent material is hydroxypropylmethylcellulose (HPMC), as well as polyvinylacetate, and combinations thereof, but the absorbent material can also comprise one or more other substances known in the art with sulfur absorbing prowess. For example, other cellulosic materials selected from the group consisting of alkyl celluloses, hydroxyalkyl celluloses and hydroxyalkylalkyl celluloses are contemplated. Also highly suitable are other polyesters and polyalkyl- and polyalkylene esters, especially polyvinylesters. Other absorbent material available in the art is also contemplated. The absorbent material will comprise about 0 to 15% of the composition of the invention, and more desirably be within the range of about 0.1 to 5% thereof.

The components heretofore described as constituting the dry, orally administered deodorizing composition of the invention are preferably combined and processed through the use of a unique procedure known in the art as "flash-flow processing", which provides a simple and effective method of preparing such compositions. The term "flash-flow" has become recognized as referring to the conditions

of temperature and force required to transform a solid feedstock having a certain morphological and/or chemical structure into a different morphological and/or chemical form without subjecting the materials to the excess heat or other requirements inherent in other forms of processing. The resultant structure has now been referred to as a "shearform matrix." The concepts of flash-flow and shearform matrix are further described, for example, in co-owned U. S. Patent 5,236,734 issued August 17, 1993, and U. S. Patent 5,238,696 issued August 24, 1993, as well as in U. S. Patents 5,518,730, 5,387,431, 5,429,836 and 5,582,855.

As indicated above, flash-flow processing involves subjecting a feedstock to conditions of temperature and force which induce a solid feedstock to rapidly undergo such physical and/or chemical transformation. The time during which the feedstock material is subjected to temperatures is extremely short. Flash-flow processing can be accomplished either by the more preferred flash heat method or via a flash shear method, as both are described further herein.

In the flash heat process, a shearform matrix can be formed by spinning a feedstock in a "cotton candy" type fabricating type machine. In particular, a spinning machine developed by Fuisz Technologies Ltd. of Chantilly, VA and patented under U.S. Patent No. 5,427,811 and especially under U.S. 5,458,823 may be preferred for the flash-heat process. This patent describes a spinning machine which has a series of elongated heating elements arranged in between a base and a cover. The heating elements, base and cover together define a chamber into which a non-solubilized feedstock material is inserted which is capable of intraparticle flow upon application of heat and force. Means are provided for individually heating each of the elongated heating elements, and restriction means in the form of a cylindrical shell or annular plate which circumscribes the heating elements permits restrictive flow of the processed feedstock which is expelled from the chamber.

It will be appreciated by those skilled in the art that any apparatus or physical process which provides similar forces and temperature gradient conditions can also be used. For simplicity in disclosing and describing this invention, the term "flash heat" will be understood to mean a process which includes subjecting a feedstock to the

combination of temperature, thermogradients, flow, flow rates, and mechanical forces of the type produced in a candy machine or the above-referenced U. S. Patent 5,427,811, as well as other apparatus having a spinning head, such as that described in U.S. Patent No.s 5,445,769, 5,447,423 and 5,458,823 and recently allowed U.S.S.N. 08/854,344. The
5 apparatus is operated at the temperature and speed which permits flash heat of the feedstock without deterioration of any of its ingredients, and these parameters can easily be optimized by those skilled in the art.

In the flash heat process, the feedstock material is heated sufficiently to create an internal flow condition, *i.e.*, intra-particle flow, which permits part of the
10 feedstock to move at a subparticle level with respect to the rest of the mass and exit openings provided in the perimeter of the spinning head. The centrifugal force created in the spinning head flings the flowing feedstock material outwardly from the heat so that it reforms with a changed structure. The force required to discharge flowable feedstock is provided by the forces which result from the spinning head. The flash heat process has
15 been used in many cases to produce an amorphous matrix from a crystalline material, as disclosed in the aforementioned Fuisz patents. In the present invention, the feedstock includes the heretofore described components constituting the orally administered deodorizing composition. It is, however, also within the scope of the invention to process some or even one of the aforesaid components using flash-flow (flash heat or flash shear).

20 In the flash shear process, a shearform matrix is formed by raising the temperature of the feedstock material, which includes a non-solubilized carrier, to a point where the carrier undergoes intra-particle flow. The carrier component is preferably a saccharide-based material. The feedstock is advanced and ejected from an extruder or similar type of machinery while the carrier is undergoing intra-particle flow and is then
25 subjected to disruptive fluid shear forces to form multiple parts or masses.

The flash shear process can be carried out in an apparatus which has means for increasing the temperature of a non-solubilized feedstock and means for simultaneously advancing it for ejection. A multiple heating zone twin extruder can be used for increasing the temperature and advancing material feedstock. The apparatus includes a means for
30 ejecting the feedstock in a condition for shearing it to provide the shearform matrix. The

means for ejecting is in fluid communication with the means for increasing the temperature and is arranged at the point to receive the feedstock while it is in the internal flow condition. The means for ejecting the feedstock is preferably a nozzle which provides sufficient frictional gas force applied to the ejected feedstock stream to disrupt the stream
5 and form shearform masses.

An apparatus for flash shear processing of the feedstock is described in U. S. Patent 5,380,473. The means for shearing is arranged proximally to the ejector and is disposed to effect the shear of the feedstock while it is in the internal flow condition. Preferably, the means for shearing is the means for delivering fluid such as at sufficient
10 velocity and at elevated temperature against the feedstock stream as it exists a nozzle. Such a device can be an external atomizing nozzle. The means for shearing can also be a chamber in which the environment can be maintained to induce shear upon the collision of a high velocity of a stream of feedstock directed against a preselected and maintained environment. The individual components of the novel composition herein described may
15 thus be subjected to flash shear processing as well. Those skilled in the art may find that flash-shear methodology and parameters can be further adjusted to their particular needs.

In flash-flow processing, the time during which the feedstock material is subjected to elevated temperature is very short. In the flash-heat method, the feedstock is subjected to elevated temperature usually for only tenths of a second, and in the flash-shear
20 method the feedstock is subjected to elevated temperatures for a time on the order of seconds. This has specific benefits in situations when materials might be degraded or otherwise detrimentally affected by excessive exposure to heat.

Flash-flow processing results in increased surface area and increased solubility of the ingredients subjected thereto, and contributes to actual mixing of the
25 ingredients with each other without degradation and undesirable chemical reactions. These shearform matrix attributes, as they are often referred to, are highly desirable in a final product.

Referring now to Figures 1 and 2, the deodorizing product of the invention is produced in dry, particulate form as a result of being processed according to the unique
30 procedures herein described as flash-flow. In addition to possessing shearform matrix

attributes, the composition may also be described as having what can be referred to as
“microparticulate dispersion” qualities. Minute particles of the individual components
constituting the shearform matrix, and hence the formulation itself, are evenly mixed and
dispersed throughout the entire matrix. Figure 2 is a photo micrograph of the composition
5 of the invention. The amorphous, random structure of the material shown in Figure 2 is a
characteristic of the final composition’s microparticulate dispersion. Thus,
microparticulate dispersion refers to the final single matrix containing integrally dispersed
and combined amounts of dissimilar ingredients. As further shown in Figure 2, the
disparate material is bound up in the matrix, which in this particular embodiment is a
10 “flake”. Many of the microparticulates can be seen as small circles or spheres throughout
the matrix. Figure 2 is to be contrasted with Figure 1, which shows material prior to being
processed in the manner herein described. The Figure 1 material does not possess the
attributes of the material shown in Figure 2. Instead, there are relatively large crystalline
chunks of material without any sort of matrix structure.

15 Small granules, flakes, spicules, powders, particles, fibers and floss, etc. are
just some of the many dry forms of the product which can exit the particular flash-flow
apparatus, depending upon adjustments made to the operating parameters (including
temperature and centrifugal force, as well as the size of the openings in the spinning head).
Regardless of the desired form, all ingredients are intimately combined so that no further
20 processing is required. Just as importantly, the shearform matrix material obtained via
flash flow dissolves readily, rapidly and substantially completely in aqueous media such
as, for example, water and saliva. (It will be appreciated by those skilled in the art that
other methods of processing the deodorizing formulation of the invention, which yield
substantially the same attributes of shearform matrix as can be achieved with flash-flow
25 processing, are also within the scope of the invention.)

The flash flow methods herein described impart another significant and
unique advantage to the product of the invention. As a result of flash-flow processing, the
dry material is substantially free of moisture, to a significantly greater extent than had the
individual components been combined using standard mixing apparatus. The overall effect
30 can not be understated. Excess moisture which is eliminated during the flash flow process

can not then be present as a medium within which the components of the composition can react, and thereby render the composition unpalatable during storage. The composition appears to be almost moisture-resistant as a result of flash-flow processing, until it is dissolved in the mouth or in water sufficient to yield a serving thereof. In contrast to the inventive composition, many so-called breath deodorizing or mouthwash formulations commercially available today are in liquid form. These require large, cumbersome and bulky packaging, i.e. plastic bottles in order to be marketed. In many instances, it is simply not possible to have these compositions in dry form, because they are not storage stable. The consumer is then left with the option of toting around bottles of mouthwash, whether small or large, which often break open in compartments such as purses and pockets. The novel composition of the invention is storage stable in its dry form for a substantially long time period, and therefore may be housed in easy to use, tear-open foil-type packages.

It is also considered a significant advance in the art of flash-flow processing to successfully process a formulation such as the dry particulate deodorizing composition herein described. Many of the active ingredients which make up the formulation are not only highly heat sensitive, but can often degrade quite quickly upon exposure to basic ambient (room temperature) conditions. In addition, many of these materials are known to react rather readily with one another. Up until now, it had been anticipated that these ingredients would either vaporize in the flash-flow apparatus, or would neutralize one another due to the excessive co-mingling which flash-flow brings about. To the contrary, it has now been found that these materials can be processed to yield a final formulation in which all ingredients are intimately mixed and preserved, but which are not reacted with one another such that their effectiveness is neutralized.

Another advantage of the composition according to the various embodiments herein described is that as a result of flash-flow processing, the formulation may be tabletted into standard, bite size lozenges and single-serving tablets. Standard tablet presses known to the skilled artisan may be utilized for this purpose. It has now been further found that the material to be tabletted can be in the form of granules, particulates, flakes and spicules, etc. prior to entering the tablet press. Typically, shearform matrix material has been in the form of fiber or floss prior to being tabletted into dosage forms for

pharmaceutical applications. Floss requires chopping, however, in order to enhance the flowability of the material. The composition of the invention, therefore, represents a further advance in the state of the art of processing shearform matrix material.

Unlike the case with many other breath-freshening tablets which are
5 commercially available, the tabletted lozenges of the invention dissolve rapidly in the mouth, preferably in under about 30 seconds or even less time. There is no need for the end user to be left sucking on a standard breath mint in social and business situations where this would not be desirable. The consumer can quickly deodorize his/her breath by dissolving the tabletted formulation rapidly and completely in the mouth. Further, because
10 the composition of the invention is available in dry form, individuals do not need to tote around bottles of mouthwash which are bulky and which tend to spill their contents. Yet the composition herein set forth compares favorably with all commercial brands of mouthwashes sold over-the-counter in liquid form. It is therefore considered to be a further advance in the art to formulate a mouthwash in dry, non-liquid form which can replace
15 many of the liquid products available today.

Another advantage of the formulation of the invention as compared with commercially available products today is that the composition herein described is substantially ethanol-free. In other words, consumers now have an alternative to liquid products which are as much as 20 - 25% by weight of ethyl alcohol. The product herein
20 described will freshen breath and clean and deodorize the mouth without this carrier.

To prepare the dry deodorizing composition for consumption, the user may first dissolve a pre-set amount in an excess of suitable liquid such as a half glass of water. More preferably, the composition may simply be placed in the mouth as is (e.g., dry flakes or dry tablet form), and allowed to dissolve with the action of saliva or other aqueous
25 media. The composition is then swished around the mouth to provide rinsing action and a cooling, refreshing vapor action sensation. Movement inside the mouth aids in contacting the mucous membranes and in reaching between the teeth to neutralize chemical odors and kill the living organisms which cause bad breath. The composition may then be expunged from the mouth. Alternatively, the composition is swallowed to allow the active
30 ingredients to act on the sources of malodor, e.g. garlic, onion, etc., in the stomach and

digestive tract. In this way, the sources of odor in the gut can be neutralized and thereby eliminated so that no malodor emanates therefrom to escape via the mouth or pores of an individual. A suitable serving size can vary according to the particular desires of the skilled artisan, but is usually within the range of about 0.1 to 50 grams, preferably about 0.3 to 20 grams. Volume-based serving sizes, e.g. one or two teaspoons or tablespoons, are also within the scope of the invention.

The composition herein described may be further utilized as part of a larger confectionery formulation in that it can comprise one ingredient in a candy, mint, chewing gum or other edible delivery system. The composition may be easily blended therein by traditional mixing methods.

The following examples are provided by way of illustration only, and are not to be construed as limiting the scope of the invention:

EXAMPLES -

Example 1 -

A dry, deodorizing formulation for oral administration was prepared with components as set forth in TABLE 1 below:

TABLE 1

Component	Qty %
Polydextrose	42 - 47%
Isomalt (Type PF)	42 - 47
Sweetener*	0.1 - 1.0
Oleaginous Material**	3.0 - 5.0
Anethole NF Extra (Polarome)	0.005 - 0.015
Alpha-Ionone	0.001 - 0.004
Cardamon Oil	0.001 - 0.004
Flavoring Agent(s)***	0.15 - 0.25
Cellulosic Material	2.5 - 3.5
Menthol	3.0 - 4.0
Eucalyptol	0.01 - 0.08
Thymol Crystals	0.02 - 0.10
Metallic Ion(s)*+	0.0025 - 0.0075

* High-intensity, artificial sweetener - typically, aspartame.

** A combination of Canola and MCT oils.

*** One or more of peppermint, spearmint, wintergreen and cinnamon.

*+ One or more of copper gluconate, zinc gluconate, and sodium copper chlorophyllin.

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All ingredients were combined using standard mixing equipment and then processed in a flash-flow processor to yield small, light-colored granules. A small portion of the mix dissolved quickly and completely in the mouth. The resulting liquid was minty and very pleasant-tasting, and quickly freshened the mouth. No evidence of malodor was observed coming from the mouth, stomach or other parts of the body for several hours thereafter. In addition, a portion of the composition from TABLE 1 was tabletted using a standard food industry hand-worked tablet press. The resulting lozenge also dissolved rapidly in the mouth, and provided the same deodorizing and cleansing prowess.

10

15 Example 2 -

A dry, deodorizing formulation for oral administration was prepared with components as set forth in TABLE 1 above, with the exception that additional menthol (up to about 7%) was utilized to provide an even more cooling, vapor action sensation. A corresponding amount of polysaccharide material was reduced.

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Example 3 - SENSORY RESULTS

Sensory data was obtained in-house on the formulation prepared from TABLE 1, with several volunteers rating that formulation (dry form), along with LISTERINE® and SCOPE® liquid mint-flavored mouthwashes and HALLS® mentholated cough drops.

25

Testers were successively given (in random order) a 20 mL. sample of each of the two liquid products, a 0.8 gram sample of the composition of the invention, and a commercial serving-size "cube" of cough drop, and asked to "rinse" their mouths with each sample for 20 seconds. The panelists were instructed to swallow the product of the invention after rinsing, and expectorate the others. Each tester was then instructed to assign the sample a hedonic score of between 1 and 10 for each of the following criteria: flavor, mouthfeel, vapor action, cooling sensation, bitterness, burning sensation, sweetness and melt characteristics. The higher the rating, the more positively the product's attribute was

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judged by the tester. The scores for the attributes were then totaled for each product. The mean total score for the four products was 47.54, with all total scores within approximately 1.5 points of the mean. This indicated that all products had comparable subjective sensory ratings. This further indicates that a dry mouthwash formulation can provide the same
5 sensory qualities as well-established commercial liquid brands, as well as cough drops.

Example 4 - SENSORY RESULTS

In this example the product of the invention was compared with LISTERINE brand mouth wash by an independent testing firm, Woelfel Research, Inc. of Vienna, Virginia.

10 Following the protocol set forth in Example 3, twelve testers chosen from the public were asked to rate the product of the invention (embodiment according to TABLE 1) with LISTERINE mint-flavored mouthwash on a hedonic scale of 1 to 10 according to the following criteria: flavor, texture, vapor action, cooling, breath freshening and overall. The results are graphed in Figure 3. The results again indicate that the dry mouthwash product
15 of the invention has comparable or even better sensory qualities than does the commercial brand, and is available in dry, particulate form with no alcohol. Figures 4 - 7 are graphs of the results obtained from the twelve panelists who then rated the effects of the respective products for up to 15 minutes after rinsing or swallowing, respectively, for the following criteria: breath freshening intensity, flavor intensity, intensity of coolness in the throat, and
20 intensity of coolness in the nasal cavity. Again, the results clearly indicate that the dry breath-freshening and deodorizing formulation of the invention in just one of its embodiments is highly competitive with the best-selling commercial liquid brand of mouthwash.

25 While the invention has been described in each of its various embodiments, it is within the scope thereof that certain modifications thereto may be effected by those skilled in the art without departing from the invention's true spirit and scope, as set forth in the description and the following claims.

CLAIMS:

What is claimed is:

1. A dry deodorizing composition for oral administration, comprising:
 - a) at least one carrier material selected from the group consisting of saccharide material;
 - b) at least one processing aid selected from the group consisting of oleaginous substances.
 - c) at least one active ingredient which is selected from the group consisting of deodorizing substances, wherein said deodorizing substances comprise metallic ions, ionone/ketone terpene compounds, menthol, menthone, thymol, eucalyptus, cardamon oil, mushroom extract, ginseng, parsley seed extract and sunflower oil; wherein said composition has sustained mouth-cleansing and deodorizing action.
2. The composition of Claim 1, wherein said deodorizing substance is capable of neutralizing internal body odors that emanate from an animal's mouth, gut, pores and other internal cavities.
3. The composition of Claim 1, wherein said composition is in shearform matrix and has a microparticulate dispersion, and further wherein said deodorizing substance is provided as part of an encapsulated matrix therein.
4. The composition of Claim 3, wherein said saccharide material is at least one member selected from the group consisting of polydextrose and maltodextrin.
5. The composition of Claim 4, wherein said deodorizing substance is at least one member selected from the group consisting of metallic ions, ionone/ketone terpene compounds, cardamon oil, menthol, thymol and eucalyptus.

6. The composition of Claim 5, further comprising at least sweetener or flavoring agent.
7. The composition of Claim 6, further comprising at least one absorbent material.
8. The composition of Claim 7, wherein said absorbent material is at least one member selected from the group consisting of hydroxyalkyl(alkyl)cellulosic material and polyalkyl esters.
9. The composition of Claim 8, wherein said composition is in granule, tablet or lozenge serving size form and is highly storage stable, yet dissolves in aqueous media in less than about 30 seconds.
10. The composition of Claim 9, wherein said active ingredient comprises at least one metallic ion selected from the group consisting of copper gluconate, zinc gluconate, and sodium copper chlorophyllin, and further comprises cardamon oil and alpha-ionone, wherein said composition is alcohol-free.

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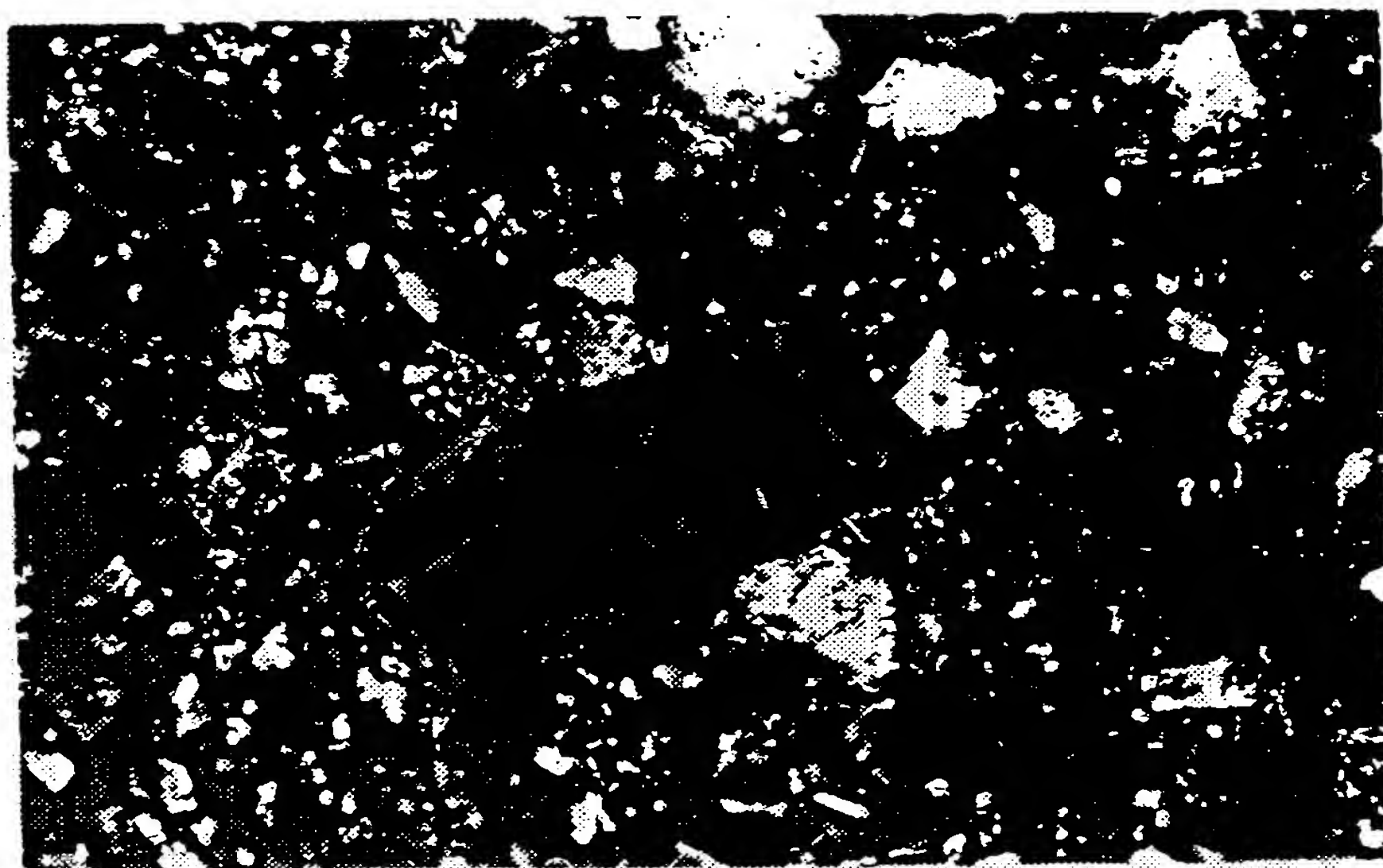


FIG. 1

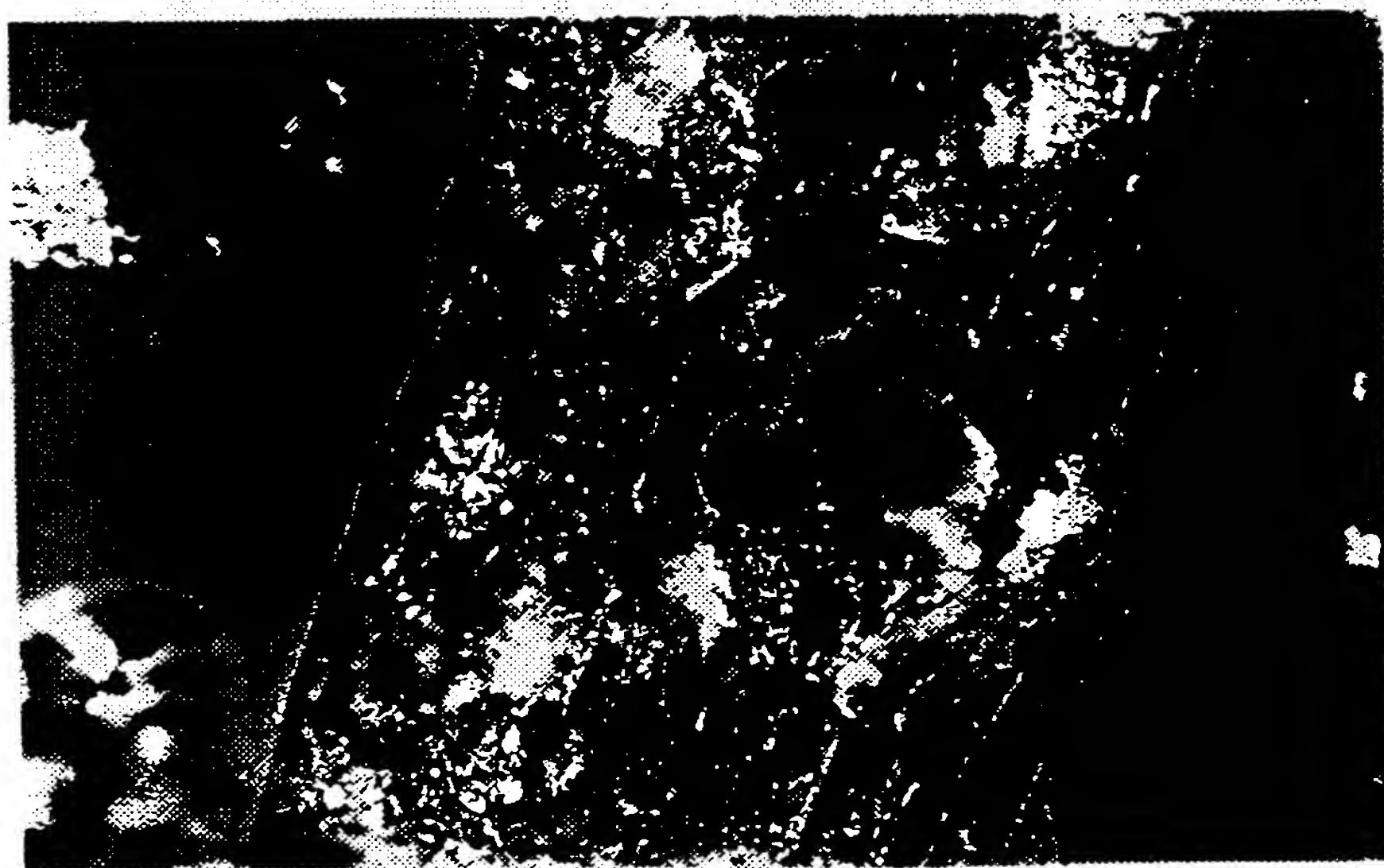
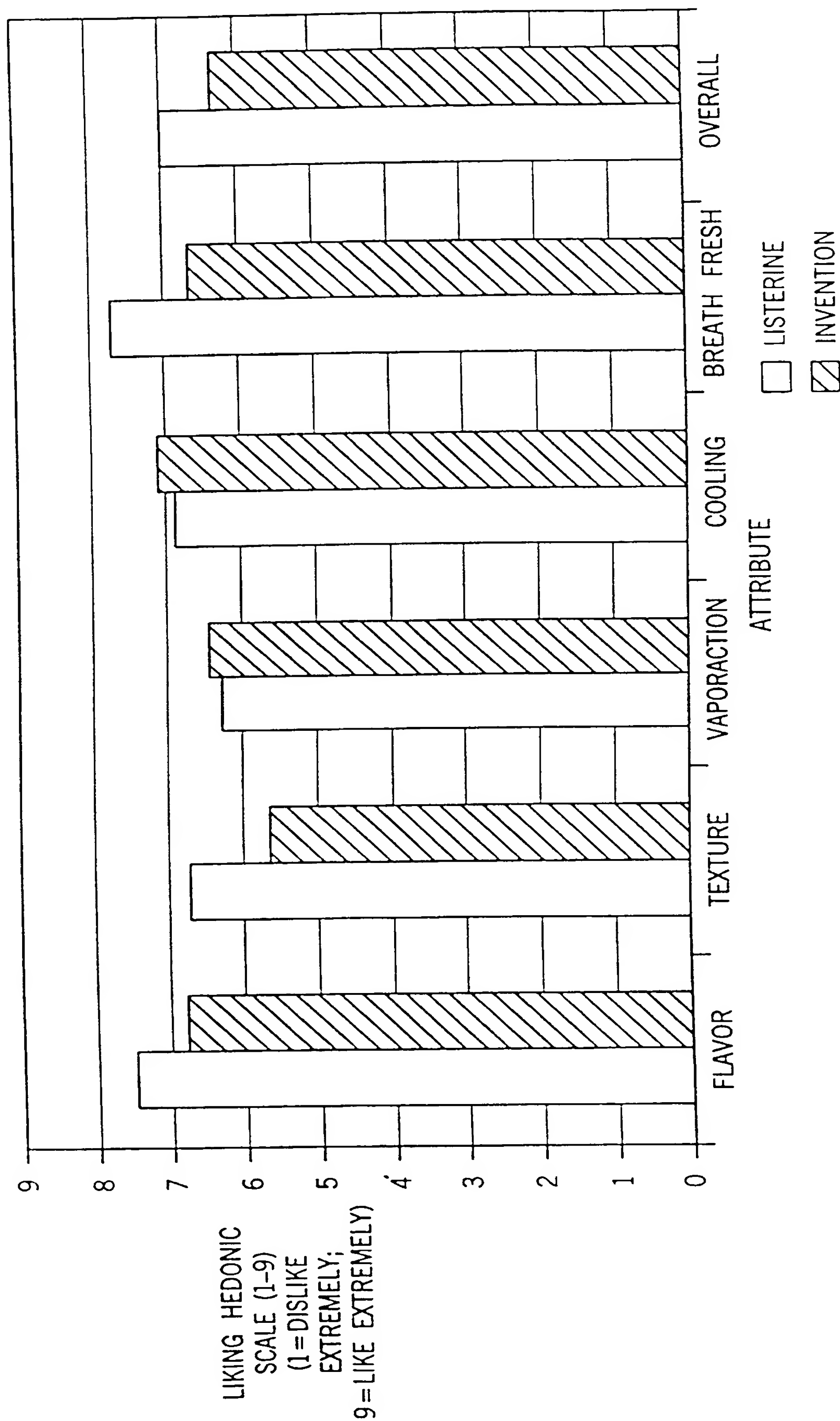


FIG. 2

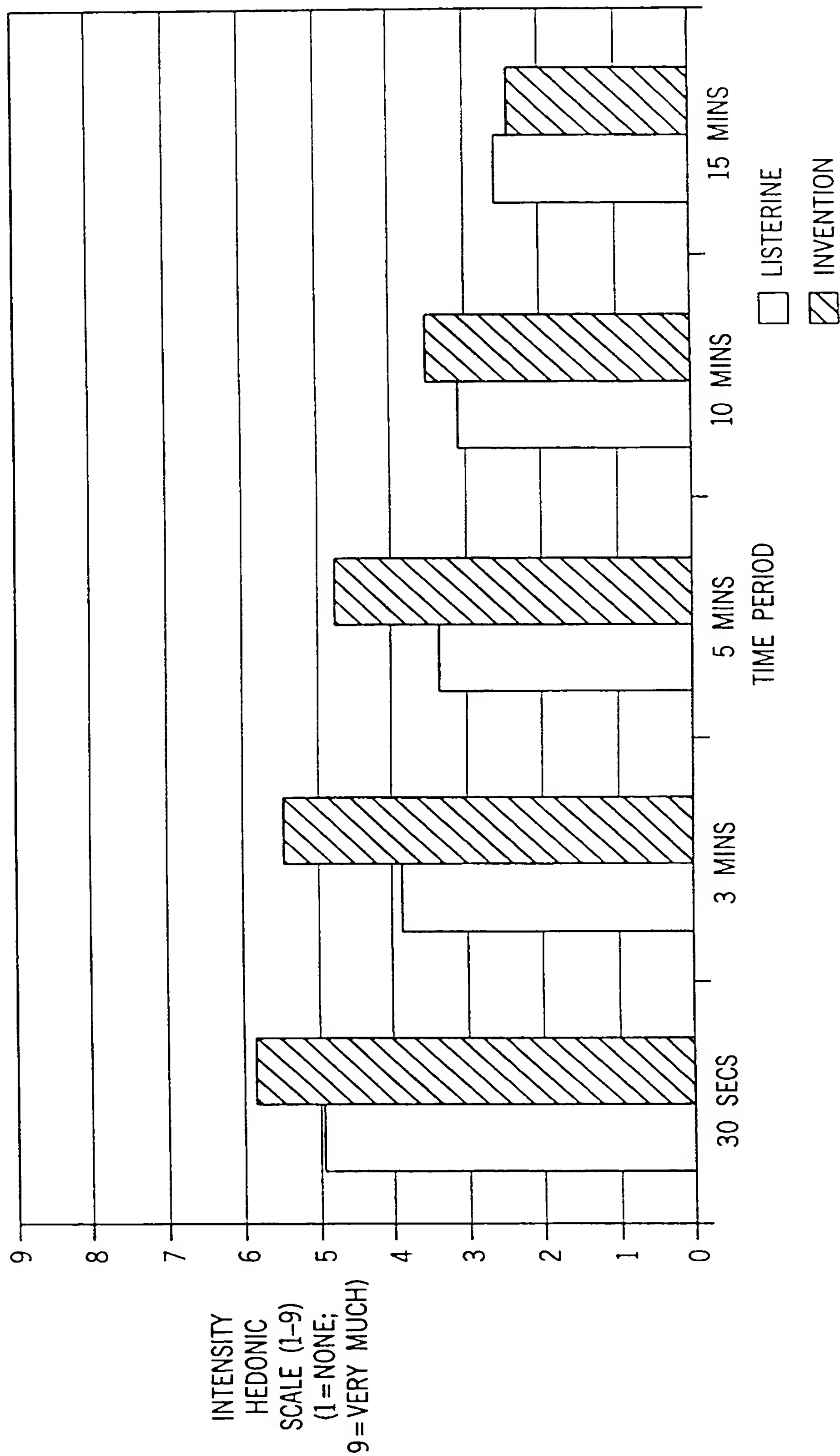
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FIG. 3



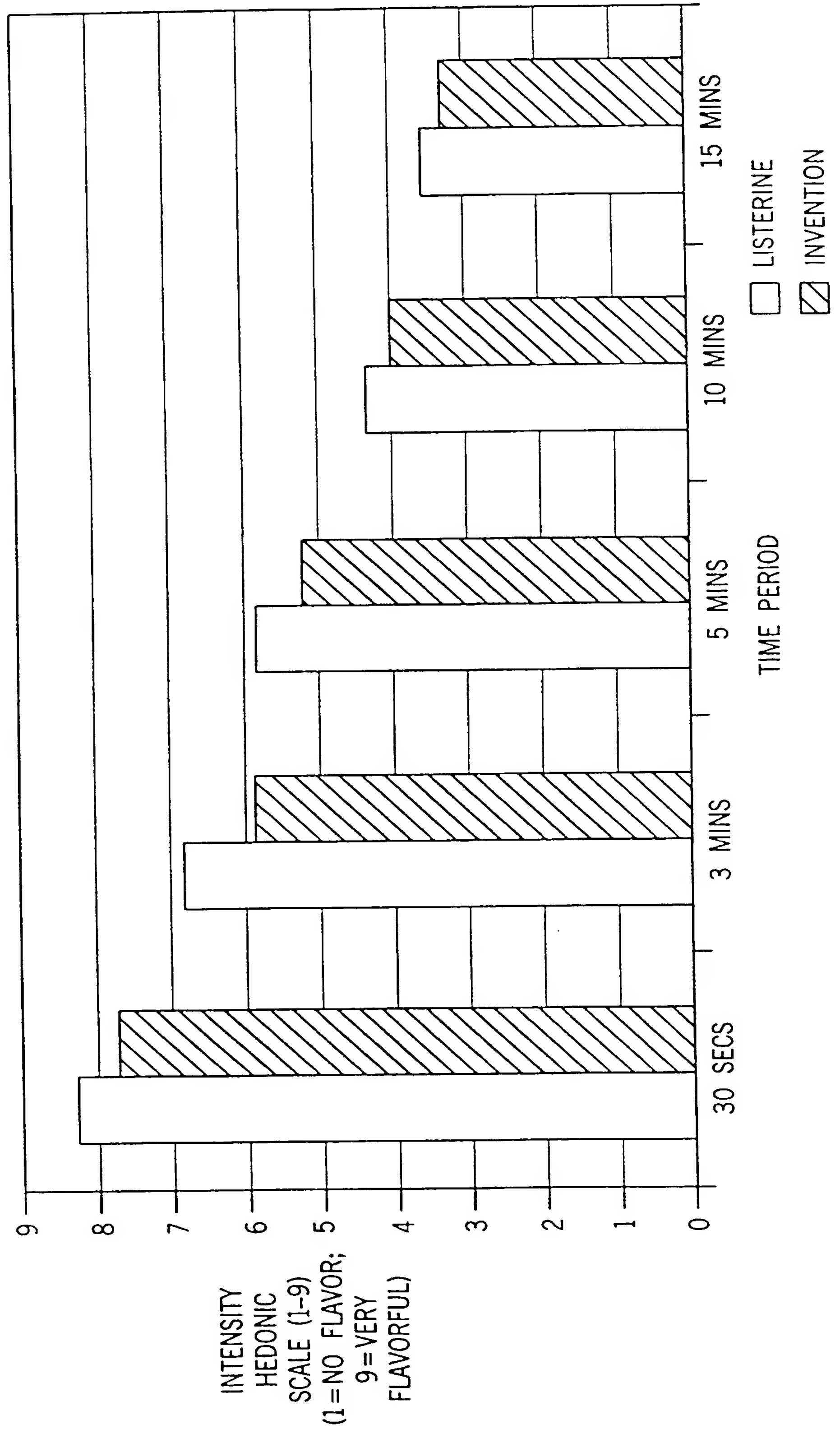
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FIG. 4



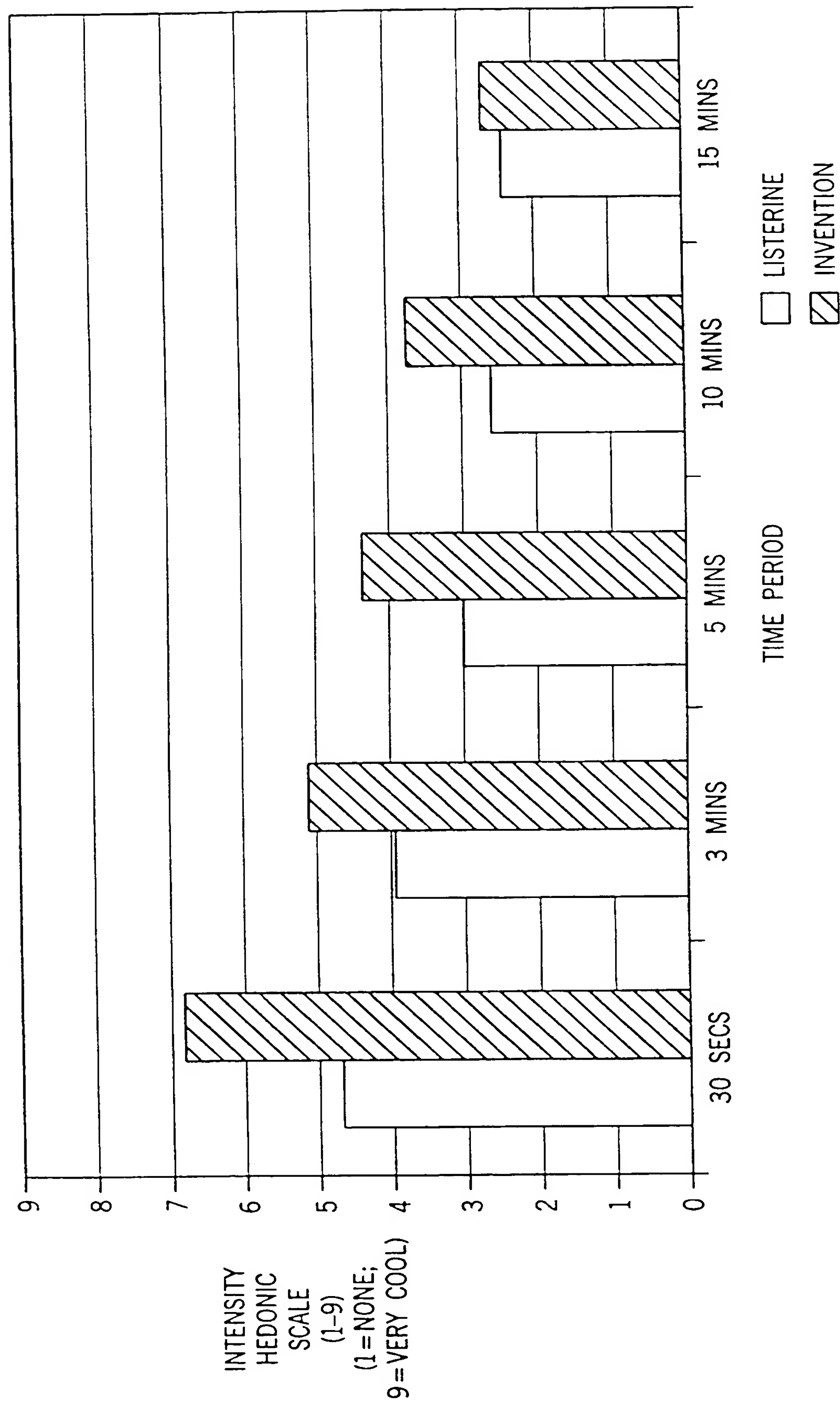
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FIG. 5



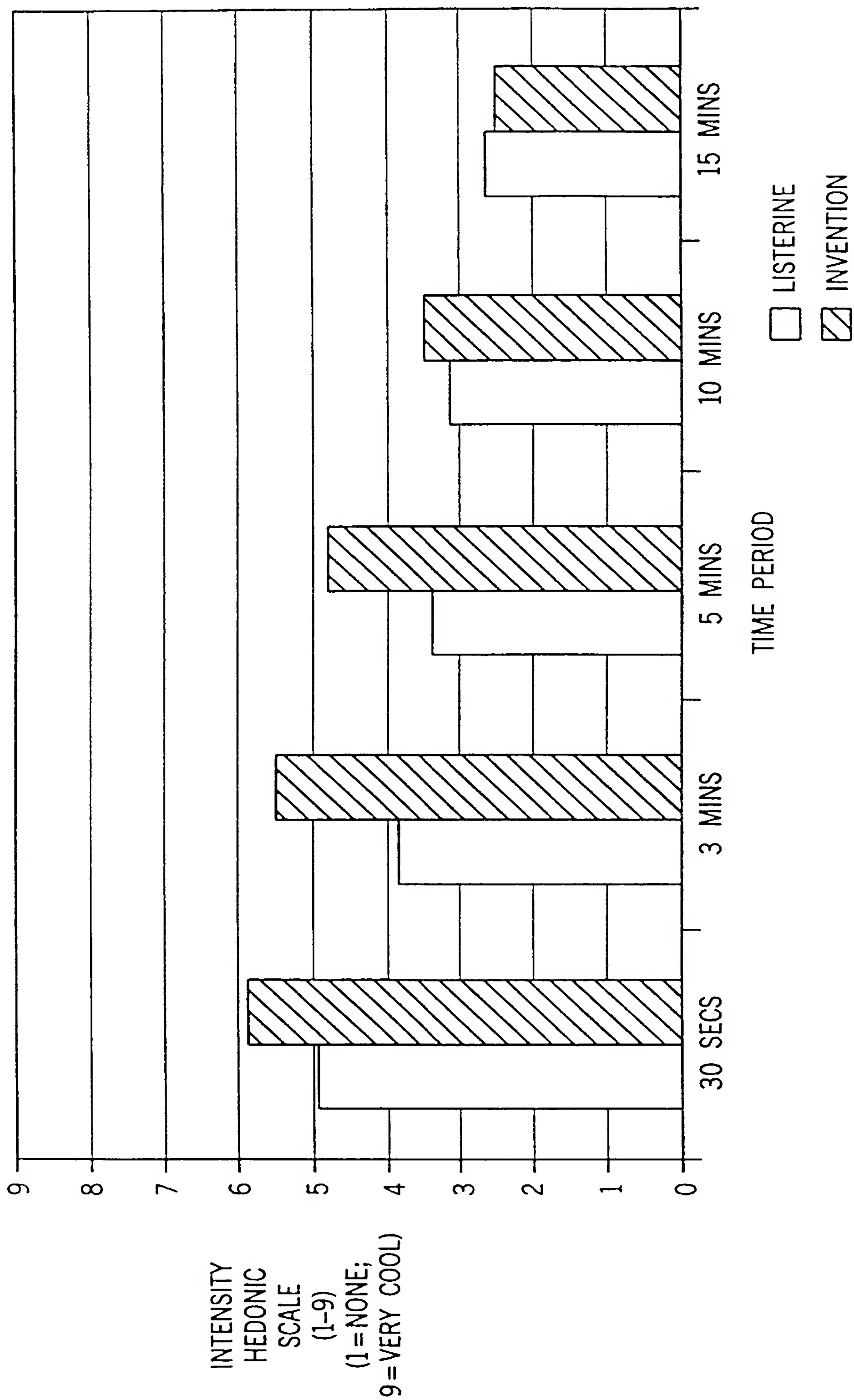
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FIG. 6



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FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/23811

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 08699 A (FUISZ TECHNOLOGIES) 13 May 1993 (1993-05-13) the whole document	1-10
X	WO 98 42316 A (SCHERER) 1 October 1998 (1998-10-01) example claims 1-12	1,2
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X	GB 2 233 228 A (WARNER-LAMBERT) 9 January 1991 (1991-01-09) the whole document	1,2,4-8
-/-		



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

10 February 2000

Date of mailing of the international search report

18/02/2000

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/23811

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 03894 A (FUISZ TECHNOLOGIES) 15 February 1996 (1996-02-15) the whole document	1-6
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E	WO 99 51211 A (FUISZ TECHNOLOGIES) 14 October 1999 (1999-10-14) the whole document	1-6
A	EP 0 711 547 A (FUISZ TECHNOLOGIES) 15 May 1996 (1996-05-15) the whole document	1-10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 23811

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99 23811

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Present claims 1-10 relate to an extremely large number of possible products. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds/products/apparatus/methods claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, and in the general view of the invention.

Claims searched: 1-10 partially

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

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